

Modified Form PTO-1449

Atty. Docket No. A-398-US-CNT3

Serial No. 10/621,784

**LIST OF REFERENCES CITED BY APPLICANT**

(Use several sheets if necessary)

Applicant

Bendele et al.

Filing Date

July 16, 2003

Group

1649

Christina Borgeest

**U.S. PATENT DOCUMENTS**

EXAMINER'S INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	A001	4,935,343	Jun 19, 1990			
	A002	4,968,607	Nov 6, 1990			
	A003	5,041,554	Aug 20, 1991			
	A004	5,075,222	Dec 24, 1991			
	A005	5,359,032	Oct 25, 1994			
	A006	5,453,490	Sep 26, 1995			
	A007	5,455,330	Oct 3, 1995			
	A008	5,508,262	Apr 16, 1996			
	A009	5,739,282	Apr 14, 1998			
	A010	5,770,401	Jun 23, 1998			
	A011	6,159,460	Dec 12, 2000			
	A012	09/326,260	Jun 4, 1999			
	A013	10/265,037	Oct 4, 2002			
	A014					
	A015					
	A016					
	A017					
	A018					
	A019					
	A020					
	A021					
	A022					
	A023					
	A024					
	A025					
	A026					

EXAMINER:

Date Considered:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CB/

<b>Modified Form PTO-1449</b>  <b>LIST OF REFERENCES CITED BY APPLICANT</b>  (Use several sheets if necessary)	Atty. Docket No.	A-398-US-CNT3	Serial No.	10/621,784
	Applicant			
	Bendele et al.			
	Filing Date	July 16, 2003	Group	1649
			Christina Borgeest	

**FOREIGN PATENT DOCUMENTS**

EXAMINER'S INITIALS		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION	
							YES	NO
	B001	AU 649245	May 19, 1994	Australia				
	B002	EP 0 343 684 B1	Apr 21, 1993	EPO				
	B003	EP 0 398 817 A1	Nov 22, 1990	EPO				
	B004	EP 0 541 920 A1	May 19, 1993	EPO				
	B005	EP 0 855 404 A1	Jul 29, 1998	EPO				
	B006	WO 91/00742 A1	Jan 24, 1991	PCT				
	B007	WO 91/08285 A1	Jun 13, 1991	PCT				
	B008	WO 91/17184 A1	Nov 14, 1991	PCT				
	B009	WO 91/17249 A1	Nov 14, 1991	PCT				
	B010	WO 92/11359 A1	Jul 9, 1992	PCT				
	B011	WO 93/07863 A1	Apr 29, 1993	PCT				
	B012	WO 93/08304 A1	Apr 29, 1993	PCT				
	B013	WO 93/08819 A1	May 13, 1993	PCT				
	B014	WO 93/18783 A1	Sep 30, 1993	PCT				
	B015	WO 93/21946 A1	Nov 11, 1993	PCT				
	B016	WO 93/24134 A1	Dec 9, 1993	PCT				
	B017	WO 94/06457 A1	Mar 31, 1994	PCT				
	B018	WO 95/16706 A1	Jun 22, 1995	PCT				
	B019	WO 95/29683 A1	Nov 9, 1995	PCT				
	B020	WO 96/00081	Jan 4, 1996	PCT				
	B021	WO 96/09323 A1	Mar 28, 1996	PCT				
	B022	WO 96/12022 A1	Apr 25, 1996	PCT				
	B023	WO 96/23067 A1	Aug 1, 1996	PCT				
	B024	WO 97/32597 A1	Sep 12, 1997	PCT				

EXAMINER:

/Christina Borgeest/ (09/29/2008)

Date Considered:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CB/

[illegible]

Date Considered:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CB/

Modified Form PTO-1449  <b>LIST OF REFERENCES CITED BY APPLICANT</b>  (Use several sheets if necessary)	Atty. Docket No.	Serial No.
	A-398-US-CNT3	10/621,784
	Applicant	
	Bendele et al.	
	Filing Date	Group
	July 16, 2003	1649
	Christina Borgeest	

EXAMIN. INITIALS

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	C001	Arend et al., "AN IL-1 INHIBITOR FROM HUMAN MONOCYTES - Production and Characterization of Biologic Properties", J. Immunol., 143(6):1851-1858 (1989).
	C002	Balavoine et al., "Prostaglandin E <sub>2</sub> and Collagenase Production by Fibroblasts and Synovial Cells is Regulated by Urine-derived Human Interleukin 1 and Inhibitor(s)", J. Clin. Invest., 78:1120-1124 (1986).
	C003	Beck et al., "Production of Interleukin 1 and A C1q Induced Interleukin 1 Inhibitor by B-CLL Cells", RES 1987 Annual Meeting (Abstract No. 232).
	C004	Bendele et al., "Effects of Interleukin-1 Receptor Antagonist Alone and in Combination with Methotrexate in Adjuvant Arthritic Rats", Arthritis & Rheumatism, 40(9 Suppl.) Abstract 889 pg. S181 (1997)
	C005	Bendele et al., "Effects of Interleukin 1 Receptor Antagonist Alone and in Combination with Methotrexate in Adjuvant Arthritic Rats", The Journal of Rheumatology, 26(6):1225-1229 (1999).
	C006	Billingham et al., "Interleukin-1: Its Relevance to Rheumatoid Arthritis", British J. Rheum., 24 (suppl. 1):25-28 (1985).
	C007	Bondeson et al., "The Mechanisms of Action of Disease-Modifying Antirheumatic Drugs: A Review with Emphasis on Macrophage Signal Transduction and the Induction of Proinflammatory Cytokines", General Pharmacology, 29(2), 127-150, (1997)
	C008	Bowie et al., "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions", Science, 247:1306-1310 (1990).
	C009	Brown et al., "Mechanism of Action of a Human Interleukin-1 Inhibitor", J. Leukocyte Biol., 37:688-689 (Abstract) (1985).
	C010	Buchan et al., "Production of Immunoregulatory mRNA Species Within the Rheumatoid Joint", Third Annual General Meeting of the British Society for Rheumatology, London, England, November 19-21, 1986, J. Rheumatol., 25(2), Abstract 113 (1986).
	C011	Carter et al., "Purification, cloning, expression and biological characterization of an interleukin-1 receptor antagonist protein", Nature, 344:633-638 (1990).
	C012	Choy et al., "Mechanisms of Action of Second-line Agents and Choice of Drugs in Combination Therapy", Clinical & Experimental Rheumatology, 17(6):S20-S28 (1999).
	C013	Choy et al., "How Do Second-line Agents Work?", British Medical Bulletin, 51(2):472-491 (1995).
	C014	Cominelli et al., "Interleukin-1 in the pathogenesis of and protection from inflammatory bowel disease", Biotherapy, 1(4):369-375 (1989).
	C015	Crilly et al., "Interleukin 6 (IL-6) and Soluble IL-2 Receptor Levels in Patients with Rheumatoid Arthritis Treated with Low Dose Oral Methotrexate", J. of Rheumatology, 22(2):224-226 (1995).
	C016	Cronstein et al., "Mechanisms of the Effects of Methotrexate", Bulletin on the Rheumatic Diseases, 45(5):6-8 (1996).
	C017	Cronstein et al., "Molecular Therapeutics", Arthritis & Rheumatism, 39(12):1951-1960 (1996).
	C018	Cutolo et al., "Anti-inflammatory Mechanisms of Methotrexate in Rheumatoid Arthritis", Annals of the Rheumatic Diseases, The Eular Journal, 60(8):729-735(2001).
	C019	Cutolo, et al., "Antiproliferative and Antiinflammatory Effects of Methotrexate on Cultured Differentiating Myeloid Monocytic Cells (THP-1) But Not on Synovial Macrophages from Patients with Rheumatoid Arthritis", J of Rheumatology, 27(11):2551-2557 (2000).
EXAMINER:		Date Considered:
/Christina Borgeest/ (09/29/2008)		
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CB/

Modified Form PTO-1449  <b>LIST OF REFERENCES CITED BY APPLICANT</b>  (Use several sheets if necessary)	Atty. Docket No.	Serial No.
	A-398-US-CNT3	10/621,784
	Applicant	
	Bendelet et al.	
Filing Date	Group	
July 16, 2003	1649	Christina Borgeest

EXAMIN. INITIALS	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
------------------	--

	C020	Dinareello et al., "Interleukin-1", Digestive Diseases & Sciences, 33(3):25S-35S (1988).
	C021	Dinareello et al., "Interleukins", Ann. Rev. Med., 37:173-178 (1986).
	C022	Drevlow et al., "Phase I Study of Recombinant Human Interleukin-1 Receptor (RHU IL-1R) Administered Intra-articularly in Active Rheumatoid Arthritis", Arthritis and Rheumatism, 36(9):S39 (Abstract 3) (1993).
	C023	Duff et al., "Immunoassay, Bioassay and In Situ Hybridization of Monokines in Human Arthritis", Monokines and Other Non-Lymphocytic Cytokines, M. Powanda et al. (eds), pp. 387-392 (Alan R. Liss, Inc.) (1988).
	C024	Durum et al., "Interleukin 1: An Immunological Perspective", Ann. Rev. Immunol., 3:263-287 (1985).
	C025	Eisenberg et al., "Primary Structure and Functional Expression from Complementary DNA of a Human Interleukin-1 Receptor Antagonist", Nature, 343:341-346 (1990).
	C026	Ferrara, "The Role of Interleukin 1 (IL-1) and IL-1 Receptor Antagonist in Graft-Versus-Host Disease", Keystone Symposium on Cellular Immunity & the Immunotherapy of Cancer, March 17-24, 1993, pg. 96 (Abstract No. NZ 019).
	C027	Fontana et al., "Interleukin 1 Activity in the Synovial Fluid of Patients with Rheumatoid Arthritis", Rheumatology Int., 2:49-53 (1982).
	C028	Furst, Daniel E., "Clinical Pharmacology of Combination DMARD Therapy in Rheumatoid Arthritis", J. of Rheumatology, 23(suppl. 44):86-90 (1996).
	C029	Girardin et al., "Tumor Necrosis Factor and Interleukin-1 in the Serum of Children with Severe Infectious Purpura", New England Journal of Medicine, 319(7):397-400 (1988).
	C030	Hall, "Isolation and Partial Purification of an Inhibitor to Interleukin I," a dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University, VCU, Richmond, VA, pgs. 1-218 (December 1985).
	C031	Hannum et al., "Interleukin-1 receptor antagonist activity of a human interleukin-1 inhibitor", Nature, 343:336-340 (1990).
	C032	Katz, "Modern Management of Rheumatoid Arthritis", Am. J. Med., 79(suppl. 4C):24-31 (1985).
	C033	Korn et al., "Augmentation of IL 1-Induced Fibroblast PGE <sub>2</sub> Production by a Urine-Derived IL 1 Inhibitor", J. Immunol., 138(10):3290-3294 (1987).
	C034	Krane and Simon, "Rheumatoid Arthritis: Clinical Features and Pathogenetic Mechanisms", Advances in Rheumatology, Synderman (ed.), 70(2):263-284 (1986).
	C035	Kupper et al., "Hydrocortisone Reduces Both Constitutive and UV-Elicited Release of Epidermal Thymocyte Activating Factor (ETAF) by Cultured Keratinocytes", J. Investigative Dermatology, 87:570-573 (1986).
	C036	Lebsack et al., "A Dose- and Regimen-ranging Study of IL-1 Receptor Antagonist in Patients with Rheumatoid Arthritis", Arthritis and Rheumatism, 36(9):S39 (Abstract 2) (1993).
	C037	Liao et al., "Identification of a Specific Interleukin 1 Inhibitor in the Urine of Febrile Patients", J. Exp. Med. 159:126-136 (1984).
	C038	Liao et al., "Characterization of a Human Interleukin 1 Inhibitor", J. Immunol., 134(6):3882-3886 (1985).
	C039	Locksley et al., "Release of Interleukin 1 Inhibitory Activity (Contra-IL-1) by Human Monocyte-derived Macrophages Infected with Human Immunodeficiency Virus In Vitro and In Vivo", J. Clin. Invest., 82:2097-2105 (December 1988).
	C040	Mihara et al., "New methotrexate derivatives for the treatment of rheumatoid arthritis", Current Opinion in Anti-inflammatory & Immunomodulatory Investigational Drugs, 2(1):26-30 (2000).
	C041	Moldawer, "Interleukin-1, TNF $\alpha$ and Their Naturally Occurring Antagonists in Sepsis", Blood Purif., 11:128-133 (1993).

EXAMINER:

/Christina Borgeest/ (09/29/2008)

Date Considered:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CB/

Sheet 6 Of 7

Modified Form PTO-1449  <b>LIST OF REFERENCES CITED BY APPLICANT</b>  (Use several sheets if necessary)	Atty. Docket No.	Serial No.
	A-398-US-CNT3	10/621,784
	Applicant	
	Bendele et al.	
	Filing Date	Group
	July 16, 2003	1649 Christina Borgeest

EXAMIN. INITIALS

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	C042	Nizolek & White, "Corticosteroid and Hyaluronic Acid Treatments in Equine Degenerative Joint Disease - A Review", Cornell Vet., 71:355-375 (1981).
	C043	Novaes et al., "Low Dose Methotrexate Decreases Intraarticular Prostaglandin and Interleukin 1 Levels in Antigen Induced Arthritis in Rabbits", J. Rheumatology, 23(12) 2092-2097, (1996)
	C044	Pujol et al., "Interleukin-1 and Osteoarthritis", Life Sciences, 41:1187-1198 (1987).
	C045	Rosenstreich et al., "The Physiologic, Metabolic, and Immunologic Actions of Interleukin-1", Proceeding of a Symposium Held in Ann Arbor, Michigan, June 4-6, 1985, pp. 419-428.
	C046	Rosenstreich et al., "A Human Urine-Derived Interleukin 1 Inhibitor", J. Exp. Med., 168:1767-1779 (1988).
	C047	Saklatavala et al., "Effects of Tumour Necrosis Factor Alpha and Interleukin 1 on the Proteoglycan Matrix of Cartilage", Development of Diseases of Cartilage and Bone Matrix, Sen and Thornhill (eds.), pp. 291-298 (Alan R. Liss, Inc.) (1987).
	C048	Scala et al., "Accessory Cell Function of Human B Cells", J. Exp. Med., 159:1637-1652 (1984).
	C049	Scala et al., "Regulatory Counteraction to Interleukin 1 (IL1) Production and Activity by Inhibitory Cells and Factors", Lymphokine Res., 3:271 (Abstract) (1984).
	C050	Scala G., Matsushima K., Oppenheim J.J., "Inhibitory cells and factors that regulate the production and activities of interleukin 1 IL-1", Sero symposia publications from Raven Press, Vol. 23, Immunopharmacology, editors, Peter A. Miescher, L. Bolis, M. Ghione. New York, pp. 41-50 (1985).
	C051	Schnyder et al., "Human Monocyte or Recombinant Interleukin 1-s are Specific for the Secretion of a Metalloproteinase from Chondrocytes", J. Immunol., 138(2):496-503 (1987).
	C052	Seckinger et al., "Interleukin-1 Inhibitors", 18th Forum in Immunology, Ann. Inst. Pasteur Immunol., 138:486-488 (1987).
	C053	Seckinger et al., "A Urine Inhibitor of Interleukin 1 Activity Affects Both Interleukin 1 $\alpha$ and 1 $\beta$ But Not Tumor Necrosis Factor $\alpha$ 1", J. Immunol., 139(5):1541-1545 (1987).
	C054	Seckinger et al., "A Urine Inhibitor of Interleukin 1 Activity that Blocks Ligand Binding", J. Immunol., 139(5):1546-1549 (1987).
	C055	Seckinger et al., "Natural and Recombinant Human IL-1 Receptor Antagonists Block the Effects of IL-1 on Bone Resorption and Prostaglandin Production", J. Immunol., 145(12):4181-4184 (1990).
	C056	Seitz et al., "Methotrexate Action in Rheumatoid Arthritis: Stimulation of Cytokine Inhibitor and Inhibition of Chemokine Production by Peripheral Blood Mononuclear Cells", 34(7):602-609 (1995).
	C057	Silberberg, "Diseases of Joints", Anderson's Pathology, Kissane (ed.), II:1828-1836 (1985).
	C058	Sissons et al., "A Monocyte Derived Inhibitor of Interleukin 1 Induced by Human Cytomegalovirus", Clin. Res., 33(2):(Abstract No. 610A) (1985).

EXAMINER:

/Christina Borgeest/ (09/29/2008)

Date Considered:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CB/

Modified Form PTO-1449  <b>LIST OF REFERENCES CITED BY APPLICANT</b>  (Use several sheets if necessary)	Atty. Docket No.	Serial No.
	A-398-US-CNT3	10/621,784
	Applicant	
	Bendele et al.	
	Filing Date	Group
	October 31, 2007	1649 Christina Borgeest

**EXAMIN. INITIALS      OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	C059	Stashenko et al., "Synergistic Interactions between Interleukin 1, Tumor Necrosis Factor, and Lymphotoxin in Bone Resorption", J. Immunol., 138:1464-1468 (1987).
	C060	Stimpson et al., "Exacerbation of Arthritis by IUL-1 in Rat Joints Previously Injured by Peptidoglycan-Polysaccharide", J. Immunol., 140:2964-2969 (1988).
	C061	Sullivan et al., "Inhibition of the Inflammatory Action of Interleukin-1 and Tumor Necrosis Factor (Alpha) on Neutrophil Function by Pentoxifylline", Infection & Immunity, 56(7):1722-1729 (1988).
	C062	Tan et al., "Inhibition of Bone Resorption by a Diphosphonate: <i>in vitro</i> Interleukin 1 Studies and Phase 1 Trials in Rheumatoid Arthritis", Australian and New Zealand Rheum. Assoc., Abstract on p. 113 (1986).
	C063	Thomas et al., "Evaluation of an interleukin-1 receptor antagonist in the rat acetic acid-induced colitis model", Agents & Action, 34:187-190 (1991).
	C064	Tracey et al., "The Use of Murine T-Cell Lines to Evaluate the Effects of Several Pharmacological Agents on Interleukin-1 Activity", J. Leukocyte Biol., 37:750-751 (Abstract) (1985).
	C065	Ulich et al., "The Intratracheal Administration of Endotoxin and Cytokines. III. The Interleukin-1 (IL-1) Receptor Antagonist Inhibits Endotoxin- and IL-1-Induced Acute Inflammation", Am. J. Pathology, 138(3):521-524 (1991).
	C066	van Hilton et al., "A Report on the International Conference on Inflammation Held in Rome, October 6-11, 1991", DN&P, 5(1):59-62
	C067	Vergne et al., "Methotrexate and Cyclooxygenase Metabolism in Cultured Human Rheumatoid Synoviocytes", J of Rheumatology, 25(3):433-440 (1998).
	C068	Wooley et al., "The Effect of an Interleukin-1 Receptor Antagonist Protein on Type II Collagen-induced Arthritis and Antigen-induced Arthritis in Mice", Arthritis & Rheumatism, 36(9):1305-1314 (1993).
	C069	BREBAN, MAXIME, et al., "Therapeutic Prospects for Modification of Interleukin-1 Activity in Arthritis," Clin Immunother., 1995, 4(4), 259-264.
	C070	CAMPIERI, M. et al., "Medical treatment of inflammatory bowel disease," Current Opinion in Gastroenterology, 1992, 8:663-675.
	C071	MILLER-BLAIR, DANA, et al., "Rheumatoid arthritis: New science, new treatment," Geriatrics, June 1993, Vol. 48 No. 6, 28-30 and 35-38.
	C072	
	C073	
	C074	

EXAMINER:	/Christina Borgeest/ (09/29/2008)	Date Considered:
-----------	-----------------------------------	------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.